III. Remarks

Specification has been amended without prejudice to include a specific reference to priority applications.

Specification has also been amended without prejudice to capitalize the names of trademarks and insert generic terminology thereafter.

Claims 66 and 70 have been amended without prejudice. Support for the amendments can be found, e.g., in original claims 66 and 70.

Applicants respectfully submit that no new matter has been added by virtue of these amendments.

Claims 62-74 are now pending, with claim 68 being withdrawn from consideration.

A. Interview Summary

Applicants acknowledge the Examiner-Initiated Interview Summary of September 7, 2007, which was attached to the Office Action mailed on September 11, 2007.

Applicants note that, based on the telephone conversation of December 5, 2007, between Examiner Alstrum-Acevedo and the Applicants' attorney, Oleg Ioselevich, Applicants' Interview Summary for the teleconference of September 7, 2007 is not being provided, as neither the claims, rejections nor prior art documents were discussed during the teleconference of September 7, 2007.

B. Information Disclosure Statement

Applicants respectfully thank the Examiner for returning copies of Form PTO-1449s, including the twelve-page Form PTO-1449 filed on November 4, 2003.

However, Applicants respectfully note that on the returned twelve-page Form PTO-1449 filed on November 4, 2003, the Examiner indicated that copies of references listed in the FOREIGN PATENT DOCUMENTS and OTHER PRIOR ART sections thereof were not provided. Accordingly, it appears that these references were not considered by the Examiner.

Applicants submit that 37 C.F.R. 1.98 states in pertinent part:

> ... (d)A copy of any patent, publication, pending U.S. application or other information, as specified in paragraph (a) of this section, listed in an information disclosure statement is required to be provided, even if the patent, publication, pending U.S. application or other information was previously submitted to, or cited by, the Office in an earlier application, **unless**:
>
> (1)The earlier application is properly identified in the information disclosure statement and is relied on for an earlier effective filing date under 35 U.S.C. 120; and
>
> (2)The information disclosure statement submitted in the earlier application complies with paragraphs (a) through (c) of this section.

See 37 C.F.R. 1.98 (emphasis added).

Applicants submit that Information Disclosure Statement filed on November 4, 2003 identified that the twelve-page Form PTO-1449 was submitted in the parent case (US Serial No. 09/781,081).

Applicants further submit that the parent case, US Serial No. 09/781,081, in which the twelve-page Form PTO-1449 was originally submitted, has now granted as U.S. Patent No. 6,696,088. Applicants also submit that the twelve-page Form PTO-1449 was in compliance of paragraphs (a) through (c) of 37 CFR 1.98.

Therefore, Applicants assert that, in accordance with 37 C.F.R. 1.98, copies of the reference listed in the FOREIGN PATENT DOCUMENTS and OTHER PRIOR ART sections of the twelve-page Form PTO-1449 did not have to be provided, as they were provided in the parent case US Serial No. 09/781,081, which is relied upon for an earlier effective filing date under 35 U.S.C. 120, and because the Information Disclosure Statement submitted in the parent case complied with the requirements of 37 C.F.R. 1.98. See, e.g., 37 C.F.R. 1.98.

For the foregoing reasons, Applicants respectfully request that the references listed in the FOREIGN PATENT DOCUMENTS and OTHER PRIOR ART sections thereof of the twelve-page Form PTO-1449 be considered and made of record.

C. Specification

In the Office Action, the specification was objected to. The Examiner stated:

> The use of the trademarks TALWIN® ([0011]), TEMGESIC® ([0011]), EUDRAGIT®, ([0116], [0145], [0147], [0151], [0214], [0305], [0440], [0441]), AQUACOAT® ([0139], [0156], [0157]), SURELEASE® ([0140] and [0156]), OPADRY® ([0158]), and AVICEL PH 101® ([0184]) have been noted in this application. Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology.

In response, Applicants submit that the specification has been amended without prejudice to capitalize the trademarks and insert the generic terminology thereafter, and respectfully request withdrawal of the objection.

D. Claim Rejections- 35 USC § 112

In the Office Action, claims 66-68 and 70 were rejected under 35 U.S.C. § 112, second paragraph. The Examiner stated that "[c]laims 66 and 70 are indefinite because said claims recite derivatives of fentanyl, however the instant specification does not define a "fentanyl derivative." The Examiner further stated that "[t]he remaining claims are rejected as depending from a rejected claim."

In response, Applicants submit that claims 66 and 70 have been amended without prejudice to delete the term "derivative", and respectfully request withdrawal of the rejection.

E. Claim Rejections- 35 USC § 102

In the Office Action, claims 62-63, 65-67, 71, and 73-74 were rejected under 35 U.S.C. § 102(e) as anticipated by US 2004/0202717 to Mehta ("the Mehta publication").

In response, Applicants submit that the Mehta publication is a publication of U.S. Serial No. 10/409,992 filed on April 8, 2003, and published on October 14, 2004. Accordingly, Applicants submit that the 102(e) date of the Mehta publication is April 8, 2003.

The present application was filed on November 4, 2003, as a continuation of US Patent Application No. 09/781,081 filed on February 8, 2001, and claiming the benefit of U.S. provisional patent application No. 60/181,369, filed February 8, 2000.

Applicants submit that the Mehta publication is not properly citable under 35 U.S.C. §102(e) against the present application, as it was filed after effective filing dates of the present application. See, e.g., 35 U.S.C. §102(e).

Further, Applicants respectfully note that MPEP states that a rejection based on 35 U.S.C. 102(e) can be overcome by "... amending the specification of the application to contain a specific reference to a prior application ... and by establishing that the prior application satisfies the enablement and written description requirements of 35 U.S.C. 112, first paragraph." See, e.g., MPEP, section 706.02(b).

In the present case, the specification has been amended to contain a specific reference to the parent application which was filed before the 102(e) date of the Mehta publication-- US Patent Application No. 09/781,081 filed on February 8, 2001, now U.S. Patent No. 6,696,088.

Applicants further submit that the parent application satisfies the enablement requirement and written description requirement of 35 U.S.C. 112, first paragraph.

Accordingly, Applicants submit that the 102(e) rejection over the Mehta publication has been overcome. See, e.g., MPEP, section 706.02(b). (a rejection based on 35 U.S.C. 102(e) can be overcome by "... amending the specification of the application to contain a specific reference to a prior application ... and by establishing that the prior application satisfies the enablement and written description requirements of 35 U.S.C. 112, first paragraph.").

Therefore, Applicants respectfully request withdrawal of the anticipation rejection over the Mehta publication.

F. Claim Rejections- 35 USC § 103

In the Office Action, claims 64, 69-70, and 72 were rejected under 35 U.S.C. § 103(a) over the Mehta publication.

In response, Applicants submit that the Mehta publication is not properly citable as prior art against the present application, as it was filed after the effective filing date of the present application, for the reasons articulated above with regard to the anticipation rejection over the Mehta publication.

Accordingly, withdrawal of the obviousness rejection over the Mehta publication is respectfully requested.

G. Double Patenting Rejections

In the Office Action, claims 63 and 71-72 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 48, 51, and 56 of copending Application No. 10/389,238.

In response, Applicants acknowledge the provisional double patenting rejection and submit that filing of a terminal disclaimer will be considered upon indications that claims are otherwise allowable.

In the Office Action, claims 62-63 were provisionally rejected on the ground of non-statutory obviousness-type double patenting over claim 41 of copending Application No. 10/401,111.

In response, Applicants acknowledge the provisional double patenting rejection and submit that filing of a terminal disclaimer will be considered upon indications that claims are otherwise allowable.

In the Office Action, claims 62-64 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 2-3 and 15-17 of copending Application No. 10/524,334.

In response, Applicants acknowledge the provisional double patenting rejection and submit that filing of a terminal disclaimer will be considered upon indications that claims are otherwise allowable.

Claims 62 and 64 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 62-63 and 65 of copending Application No. 10/700,861.

In response, Applicants respectfully submit that claims 62 and 64 of the present application correspond to claims 62 and 64 of the parent application, U.S. Application Serial No. 09/781,081, now U.S. Patent No. 6,696,088; and claims 62-63 and 65 of copending Application No. 10/700,861 correspond to claims 65-66 and 68 of the parent application, U.S. Application Serial No. 09/781,081, now U.S. Patent No. 6,696,088.

Applicants further submit that claims 62, 64 and 65-66, 68 of the parent application were subject to a Restriction Requirement issued in the parent case on March 19, 2002. In particular, in the Restriction Requirement, the Examiner characterized claims 62 and 64 of the parent application (corresponding to claims 62 and 64 of the present application) into Group II, and claims 65-66 and 68 of the parent application (corresponding to claims 62-63 and 65 of the '861 application) into Group III. Further, the Examiner specifically stated that "[i]nventions Group II and Group III are unrelated ..." See Restriction Requirement, page 5. For the Examiner's convenience, a copy of the March 19, 2002 Restriction Requirement is enclosed as Appendix A.

The Examiner is respectfully reminded that "[w]here restriction is required by the Office double patenting cannot be held". MPEP 8th Ed. 4th Rev. §806.

Therefore, Applicants respectfully assert that because the Office has required a restriction in the parent case between claims 62 and 64 of the parent application (corresponding to claims 62 and 64 of the present application) and claims 65-66 and 68 of the parent application (corresponding to claims 62-63 and 65 of the '861 application) on March 19, 2002, the double patenting rejection between claims 62 and 64 of the present application and claims 62-63 and 65 of the '861 application "... cannot be held". MPEP 8th Ed. 4th Rev. §806.

Accordingly, Applicants respectfully request withdrawal of the double patenting rejection.

IV. Conclusion

An early and favorable action on the merits is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is requested to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____
Oleg Ioselevich
Reg. No. 56,963

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940

APPENDIX A

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,081	02/08/2001	Benjamin Oshlack	200.1133	7465

23280 7590 03/19/2002

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 SEVENTH AVENUE, 14TH FLOOR
NEW YORK, NY 10018

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Excelon 4/2 PCMan 4/2

CD 9/19/02 Office Action Response due (Deadline Date)

CD 4/19/02 Office Action Response due (1 month Date)

CD 4/12/02 Reminder

CD 4/5/02 Send Reporting letter

CMD/RJP/mmr

PTO-90C (Rev. 07-01)

Office Action Summary	Application No. 09/781,081	Applicant(s) Oshlack et al.
	Examiner Susan Tran	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-105* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-105* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-59, and 61, drawn to an oral dosage form, classified in class 424, subclass 464+.

   II. Claims 62-64, 75-80, 90-94 drawn to bi-layer dosage, classified in class 424, subclass 471.

   III. Claims 65-68, 83-89, 95 drawn to three layers dosage form, classified in class 424, subclass 471.

   IV. Claims 69-74, drawn to matrix dosage form, classified in class 424, subclass 484.

   V. Claims 96-99, drawn to a composition, classified in class 424, subclass 451+.

   VI. Claims 100-105, drawn to a composition and a method for treating pain, classified in class 424, subclass 451+.

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

   a. Layers dosage form

   b. Multiparticulates, granules, beads, pellets

   c. Coated multiparticulates

   d. Matrix

e. Cellulose polymer

f. Acrylic polymer

g. Capsule

h. Tablet

I. Sustained release tablet

j. Sustained release capsule

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-9, 41, 54, 62, 63, 65, 69, 41, 73, 96, and 100 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In this case, the oral dosage form of Group I invention does not use the core as required in the invention of Group II.

Inventions Group I and Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The oral dosage form of Group I invention does not require the third layer as the invention of Group III.

Inventions Group I and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In this

case, the composition of Group IV does not practice using the sequestered opioid antagonist required in the Group I invention.

Inventions Group I and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The composition of Group V does not require the layers as the invention of Group I.

Inventions Group I and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The composition of Group VI does not require the layers as the invention of Group I.

Inventions Group II and Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The oral dosage form of Group II invention does not require the third layer as the invention of Group III.

Inventions Group II and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In this case, the composition of Group IV does not practice using the sequestered opioid antagonist required in the Group II invention

Inventions Group II and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The composition of Group V does not require the layers as the invention of Group II.

Inventions Group II and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The composition of Group V does not require the layers as the invention of Group II.

Inventions Group III and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The dosage of Group III invention does not require the use of hydrophobic material as the invention of Group IV.

Inventions Group III and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The dosage form of Group V invention does not require the third layer as the invention of Group III.

Inventions Group III and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The dosage form of Group VI invention does not require the third layer as the invention of Group III.

Inventions Group IV and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The dosage of Group V invention does not require the use of hydrophobic material as the invention of Group IV.

Inventions Group IV and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The dosage of Group VI invention does not require the use of hydrophobic material as the invention of Group IV.

Inventions Group V and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The dosage of Group VI invention requires the present of opioid agonist, while the invention of Group V does not.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VI, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600